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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,012	02/20/2004	Pramod K. Srivastava	8449-298-999	2496
20583	7590	02/06/2006	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			SANG, HONG	
			ART UNIT	PAPER NUMBER
			1643	

DATE MAILED: 02/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/784,012

Applicant(s)

SRIVASTAVA, PRAMOD K.

Examiner

Hong Sang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

**RE: Srivastava**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-3, 7-10, 15, 17, 19, 20, 23, 25-33 and 35 drawn in part to a method of treating or preventing a type of cancer comprising administering to a subject a composition comprising (a) heat shock protein, and (b) antigenic proteins, classified in class 424, subclass 277.1.
  - II. Claims 1-3, 7-10, 15, 17, 19, 20, 23, 25-33 and 35, drawn in part to a method of treating or preventing a type of cancer comprising administering to a subject a composition comprising (a) alpha-2-macroglobulin, and (b) antigenic proteins, classified in class 424, subclass 277.1.
  - III. Claims 4-6, 11-14, 16, 18, 21, 22, 24, 25-32, 34, and 36, drawn in part to a method of treating or preventing a type of infectious disease, comprising administering to a subject a composition comprising (a) heat shock protein, and (b) antigenic proteins, classified in class 424, subclass 204.1.
  - IV. Claims 4-6, 11-14, 16, 18, 21, 22, 24, 25-32, 34, and 36, drawn in part to a method of treating or preventing a type of infectious disease, comprising administering to a subject a composition comprising (a) alpha-2-macroglobulin, and (b) antigenic proteins, classified in class 424, subclass 204.1.

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V. Claims 37-39, drawn in part to a kit comprising composition comprising (a) heat shock protein and (b) antigenic proteins, classified in class 530, subclass 350.

VI. Claims 37-39, drawn in part to a kit comprising composition comprising (a) alpha-2-macroglobulin and (b) antigenic proteins, classified in class 530, subclass 350.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions V-VI and Inventions I-IV are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the composition can be used to make antibodies as opposed to being used to treat or prevent cancer or infectious diseases.

Searching the Inventions V-VI and Inventions I-IV together would impose serious search burden. The inventions of Inventions V-VI and I-IV have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for a composition and the method of treating or preventing cancer or infectious disease are not coextensive. Inventions I-IV encompass method steps such as administering to a subject a composition, which are not required for the search of Inventions V-VI. The search for Invention I-IV would require a text search for the method of treating or preventing cancer or infectious disease. Moreover, even if the composition was known,

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the method of using it to treat or prevent cancer or infectious disease may be novel and unobvious in view of the preamble or active steps.

Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of treating or preventing cancer (groups I and II), and the method of treating or preventing infectious disease (groups III and IV) are unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material or comprises different methodological steps. For groups I and II, cancer is treated, and for groups III and IV, infectious disease is treated. Because cancer and infectious disease are completely distinct condition, therefore, groups I-II and groups III-IV are distinct. Groups I and II, and groups III-IV further differ from each other in that heat shock protein is used in groups I and III, alpha-2-macroglobulin is used in groups II and IV. Because heat shock protein and alpha-2-macroglobulin are structurally and functionally distinct, therefore, each method is divergent in materials and steps. For these reasons the Inventions I-IV are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. Searching groups I-IV are not coextensive. As such, it would be burdensome to search the inventions of groups I-IV together.

Groups V and VI are distinct because heat shock protein and alpha-2-macroglobulin are structurally and functionally distinct, which would require separate search.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. This application contains claims directed to the following patentably distinct species of the claimed invention: a chemotherapeutic agent, an anti-angiogenic agent, a cytokine, a biological response modifier, a hormone, an antibody, a polynucleotide, an immunostimulatory oligonucleotide, a photodynamic therapeutic agent and radiation.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-22 and 25-36 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145.

The examiner can normally be reached on 8:30am-5:00pm.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hong Sang  
Art Unit: 1643  
Jan. 20, 2006



LARRY R. HELMS, PH.D.  
SUPERVISORY PATENT EXAMINER